Proposed Definitions of Routine Patient Care Costs
Cancer Clinical Trials Advisory Council Meeting
October 28, 2011

MONTANA—2007 DRAFT STATEMENT—AGREEMENT NOT REACHED

IV. Costs Associated With Cancer Clinical Trials

Funding for cancer clinical trials, which covers the cost of protocol development and data collection traditionally comes from a variety of sources including pharmaceutical companies, research institutions and government agencies. (Hereafter referred to as "sponsors") Support for patient care provided in cancer clinical trials is not generally included in this funding.

There are five components of costs associated when conducting clinical trials.

1.1 **The administrative costs of the study** are borne by the sponsoring organizations and include:

- 1.1.1 Data gathering
- 1.1.2 Statistical study
- 1.1.3 Regulatory requirements
- 1.1.4 Contractual agreements
- 1.1.5 Meetings and travel

2.1 The **routine patient care costs** (conventional care) shall be provided by the patient's health plan.

- 2.1.1 Routine patient care costs are items or services that are typically covered benefits when provided outside a clinical trial.
- 2.1.2 "Routine" services include services that would be approved for coverage under the policy, even when delivered within the context of a clinical trial.
- 2.1.3 Health plans shall provide coverage for routine patient care costs incurred for drugs and devices provided to the member during the clinical trial provided that those drugs or devices have been approved for sale by the FDA, and to the extent those drugs or devices are not provided or paid for by the sponsor of the clinical trial, or the manufacturer, distributor, or provider of that drug or device.

3.1 The **costs associated in the delivery of the investigational agent** shall be borne by the health plan.

- 3.1.1 Services required solely for the provision of the investigational item shall be provided in accordance with the benefits of the patient's health plan Coverage would include procedures, drugs or devices approved for coverage for any medical indication.
- 3.1.2 The clinically appropriate monitoring of the effects of the item or service should be considered routine patient care costs.
- 3.1.3 The prevention of complications of the item or service should be considered routine patient care costs.
- 3.1.4 This coverage shall include payment for reasonable and medically necessary services necessary to administer the drug or use the device under evaluation in the clinical trial.

4.1 **Costs incurred for patient care generated specifically by the cancer clinical trial** shall be borne by the clinical trial sponsor.

4.1.1 Examples of these are costs for additional medication, laboratory studies, or diagnostic imaging.

4.1.2 The health plan's coverage of "routine costs" would *not* include non-FDA approved drugs or devices or unapproved medical procedures.

4.1.3 Coverage would *not* include diagnostic tests that are performed for investigative purposes but not necessary for the patient's medical management.

4.1.3 It would also not include services beyond the scope of the subscriber's contract.

5.1 **Costs of treating adverse side effects** experienced during treatment should be borne by the clinical trial sponsor. The clinical trial sponsor would be expected to cover medical care needed to treat any complications which were probably arising from the investigational service, when the medical services provided are otherwise covered under the subscriber contract.

5.1.1 It is recognized that while quality trials are designed with the utmost attention to patient safety, complications can occur when patients are participating in a clinical trial.

5.1.2 It is reasonable to expect that in the event of an adverse reaction, the clinical trial sponsors' commitment to offer their members treatment for any medically necessary treatment would apply.

ACA—Patient Protection and Affordable Care Act of 2010

''(2) ROUTINE PATIENT COSTS.—

''(A) INCLUSION.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

''(B) EXCLUSION.—For purposes of paragraph (1)(B), routine patient costs does not include—

''(i) the investigational item, device, or service, itself;

''(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or

''(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

MEDICARE—Final National Coverage Decision, effective October 2007

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies (LMRPs) or the regulations on category B investigational device exemptions (IDE) found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare contractors' local policies.

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Pub 100-03, NCD Manual and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.